REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim Rejections Under 35 USC § 102(b)

Applicants urge that the amended claim is no longer anticipated by US Patent No. 5,672,360 ("Sackler"). Although Sackler discloses a composition having Eudragit® RS 30 D and talc, Sackler does not suggest the use of hydrophobic silica.

In the context of the present invention, the expression "silica exhibiting a hydrophobic character" designates a hydrophobic silica. As indicated on Exhibit 3 of the previous response, there are several synonyms for silica, e.g. Aerosil or fumed silica. Degussa is the main manufacturer of Aerosil. On the website of Degussa, various grades of Aerosil are provided. In particular, Aerosil may be hydrophilic (Exhibit A) or hydrophobic (Exhibit B).

In claim 1, "silica exhibiting a hydrophobic character" designates a hydrophobic silica as described on Degussa website, and as opposed to the various hydrophilic silica, which are also available from Degussa.

The expression "silica exhibiting a hydrophobic character" does not mean any excipient with hydrophobic properties which would include talc for instance. Silica is not talc and does not encompass talc. Those two products are chemically and physically different. The following table summarizes the differences between silica and talc.

	Talc	Silica
Chemical formula	$Mg_6(Si_2O_5)_4(OH)_4$	SiO_2
Chemical family	Purified hydrated manesium silicate	Colloidal silicon dioxide
BET surface area	2.41 m^2/g	100-260 m^2/g

Therefore, the present claims are novel.

Claim Rejections Under 35 USC 103

Applicants urge that the present invention is not obvious over Sackler, who teaches a sustained release multiparticulate system for a once-a-day administration of opoid analgesic. The examples disclose in particular morphine sulfate beads with the following structure:

- sugar beads,

- an active coating containing morphine sulfate, lactose hydrous impalpable or lactose, PVP and opadry,

- a sustained-release coating containing Eudragit RS 30D and/or Eudragit RL 30D, triethylcitrate and talc,

- an immediate-release morphine sulfate over-coating containing morphine sulfate and opadry.

Accordingly, Sackler discloses a sustained-release layer containing Eudragit RS 30D and talc. However, as previously demonstrated, talc is not a hydrophobic silica. Therefore, the claims are novel over Sackler.

Sacker teaches: "After coating with the hydrophobic polymer, a further overcoat of a film-former, such as Opadry®, is optionally applied to the beads. This overcoat is provided, if at all, in order to substantially reduce agglomeration of the beads." (Col. 10, lines 57-61). Even if Sackler indicates that this overcoat is optional, all the microgranules which are exemplified in Sackler do possess this overcoating.

In the present invention, the inventors have surprisingly discovered that by introducing a relatively low amount of hydrophobic silica (0.2 to 1 %), the microgranules do not require this overcoating. This advantage is expressly mentioned page 4, lines 24-30 of the specification of the present application. Sackler does not teach nor suggest the use of a hydrophobic silica, but rather teaches the use of talc as a conventional lubricant. Therefore the present invention has an unexpected result over Sackler.

In the present invention, the sustained-release layer may also contain a conventional lubricant such as talc. However, the hydrophobic silica is introduced in the sustained-release layer in addition to this lubricant, and not in the place of this lubricant.

Conclusion

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date October 27, 2005

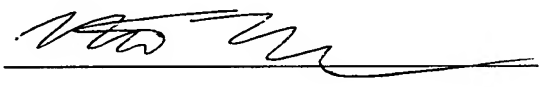
By 

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EXHIBIT A

Product Finder
Product Groups
Hydrophilic Products
Hydrophobic Products
Fumed Mixed Oxides
Fumed Metal Oxides
Special Products
Dispersions
Advanced Nanomaterials
Industries & Effects
Service Center
About us
Safety & Handling
Contact
Careers

Hydrophilic Fumed Silicas

AEROSIL® grades	BET Surface Area [m^2/g]	Loss on Drying [wt. %]	pH
AEROSIL® 90	90 ± 15	≤ 1.0	3.7 - 4.7
AEROSIL® 130	130 ± 25	≤ 1.5	3.7 - 4.7
AEROSIL® 150	150 ± 15	(≤ 0.5)*	3.7 - 4.7
AEROSIL® 200	200 ± 25	≤ 1.5	3.7 - 4.7
AEROSIL® 300	300 ± 30	≤ 1.5	3.7 - 4.7
AEROSIL® 380	380 ± 30	≤ 2.0	3.7 - 4.7
AEROSIL® OX 50	50 ± 15	≤ 1.5	3.8 - 4.8
AEROSIL® EG 50	50 ± 15	≤ 1.0	3.8 - 4.8
AEROSIL® TT 600	200 ± 50	≤ 2.5	3.6 - 4.5

The data have no binding force. Any parameter should be specified individually if necessary.
*only shrink-wrapped product

=> Productinformation and Safety Data Sheets (MSDS) can be displayed or downloaded as a pdf-file at the Productfinder

Along with the traditional polyester, silicone, paints and coating applications, hydrophilic AEROSIL® products are used with increasing success in high technology fields.The nano-sized particle nature and high purity of fumed silica play key roles in the electronics and optical fibers industries.

Furthermore, the hydrophilic AEROSIL® grades are characterized by an X-ray amorphous structure. Depending on the market and application, products with various primary particle sizes and different BET-surface areas are available. Certain types are also available in compacted form (V- and VV-grades) and in a pharmaceutical grade.

Positive Effects:

- Optimum adjustment of rheology during processing
- Reinforcement of silicone elastomers
- Thickening of non-polar liquids
- Free-flow of foodstuffs and industrial powders
- High chemical purity
- Excellent insulation properties, even at high temperatures
- Conversion from liquids to powders, e.g.medicine, cosmetics

EXHIBIT B

Hydrophobic Fumed Silicas

AEROSIL® grades	BET Surface Area [m^2/g]	Loss on Drying [wt. %]	pH	Carbon Content [wt. %]
AEROSIL® R 972	110 ± 20	≤ 0.5	3.6 - 4.4	0.6 - 1.2
AEROSIL® R 974	170 ± 20	≤ 0.5	3.7 - 4.7	0.7 - 1.3
AEROSIL® R 104	150 ± 25	-	≥ 4.0	1.0 - 2.0
AEROSIL® R 106	250 ± 30	-	≥ 3.7	1.5 - 3.0
AEROSIL® R 202	100 ± 20	≤ 0.5	4.0 - 6.0	3.5 - 5.0
AEROSIL® R 805	150 ± 25	≤ 0.5	3.5 - 5.5	4.5 - 6.5
AEROSIL® R 812	260 ± 30	≤ 0.5	5.5 - 7.5	2.0 - 3.0
AEROSIL® R 812 S	220 ± 25	≤ 0.5	5.5 - 7.5	3.0 - 4.0
AEROSIL® R 816	190 ± 20	≤ 1.0	4.0 - 5.5	0.9 - 1.8
AEROSIL® R 7200	150 ± 25	≤ 1.5	4.0 - 6.0	4.5 - 6.5
AEROSIL® R 8200	160 ± 25	≤ 0.5	≥ 5.0	2.0 - 4.0
AEROSIL® R 9200	170 ± 20	≤ 1.5	3.0 - 5.0	0.7 - 1.3

The data have no binding force. Any parameter should be specified individually if necessary.

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Numerous grades of hydrophobic AEROSIL® have been developed to solve particular technical problems. AEROSIL® Hydrophobic Fumed Silicas are produced by chemical treatment of hydrophilic grades with silanes or siloxanes. In the finished product, the treatment agent is chemically bonded to the previously hydrophilic oxide. AEROSIL® hydrophobic products are characterized, among other things, by a low moisture adsorption, excellent dispersibility, and their ability to adjust the rheological behavior, even that of polar systems.

AEROSIL® grades, like R 7200, R 8200 and R 9200, undergo additional structural modification which makes it possible to offer further support to our customers in the develop- and enhancement of their products. An example of this could be higher loading levels in liquid systems with little impact on viscosity.

Positive Effects:

- Optimum rheology during processing
- Thickening of polar liquids, e.g. epoxy resins
- Reinforcement of silicone elastomers
- High levels of loading, e.g. molding compounds
- Excellent water-repelling properties, leading to improved corrosion protection
- Improvement of dielectric properties, e.g. in cable compounds
- Free-flow of powders, e.g. in fire extinguishers
- Increased scratch resistance, e.g. in paints and plastics

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